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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,142	10/15/2001	Kazuya Kawasaki	JG-TT-5103 / 500568.20030	4088
26418	7590	11/18/2005	EXAMINER	
REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650			SIEFKE, SAMUEL P	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/978,142

Applicant(s)

KAWASAKI ET AL.

Examiner

Samuel P. Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. An organic solvent having a lower alcohol containing 1 to 4 carbon atoms or a ketone was added to claim 1 in most recent amendment. The Examiner recommends canceling claim 3.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **3-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al. (USPN 4,900,665) in view of Bell et al. (USPN 5,360,595).

Terashima discloses a method of producing a multilayer analytical element that comprises a water-impermeable transparent support (col. 3, lines 54-65), at least one water-permeable layer (col. 4, lines 24-56), and a spreading layer which is composed of polyester and has a function of spreading liquid uniformly (col. 6, lines 7-68; col. 9, line 28 and line 51-52), laminated in this order. It is desirable that a self-developing substrate is incorporated in the spreading layer so as not to be brought into contact with a buffering agent in the water-permeable layer. For example, the incorporation of a self-developing substrate in the spreading layer is performed in such a manner that a laminated structure obtained by laminating the water-permeable layer and the spreading

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layer in turn onto a support as described above is coated or impregnated with a coating solution of the self-developing substrate and optionally a surfactant and a high molecular weight compound dissolved in an organic solvent or a mixture of an organic solvent and water. Examples of such organic solvents include water-soluble polar solvents such as methanol, ethanol, propanol, acetone and acetonitrile; and hydrophobic solvents such as toluene and ethyl acetate. When the spreading layer is composed of a material to be laminated by lamination, such as woven fabric or glass fiber filter paper, the substrate may be previously impregnated, dried and then laminated. When the spreading layer is formed by coating, for example, the spreading layer is composed of a brushed polymer layer or three-dimensional lattice-form structure using microbeads, the coating solutions for the substrate and the spreading layer may be mixed together and applied. In addition to the self-developing substrate, a light blocking fine particle or reagents such as surfactant may be incorporated into the spreading layer of the analytical element of the invention. These reagents may be mixed with the coating solution for the substrate to incorporate it in the spreading layer, or the reagents and the substrate may be separately incorporated in the spreading layer by other methods. The organic solvent is a lower alcohol containing 1 to 4 carbon atoms (ethanol, acetone, col. 8, lines 35-38). The organic solvent is supplied in an amount of 30 to 90% of the spreading layer by volume (col. 11, lines 10-30; col. 12, lines 43-64). The spreading layer after the organic solvent is dried until the amount of the organic solvent coating becomes 0.1 to 5% of the supplied amount. Terashima discloses allowing ample amount of time to dry, 60 ml m<sup>2</sup> amount of the solution was added to the

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spreading layer (col. 11, lines 15-18). Terashima specifically states in addition to the self-developing substrate reagents such as surfactants may be incorporated into the spreading layer of the analytical element. Then goes on to state that these reagents may be mixed with the coating solution for the substrate to incorporate it in the spreading layer **or** the reagents and the substrate may be separately incorporated in the spreading layer by other methods (col. 8, lines 48-55). The later being of importance in the instant application.

Terashima does not teach supplying an organic solvent before the reagent solution.

Bell teaches an improved procedure for the manufacture of a diagnostic test device comprising a matrix having uniformly dispersed tetrazolium salt and a reagent system designed to convert the tetrazolium to its colored formazan upon contacting the matrix with a fluid containing an analyte whose presence and/or concentration is being sought. The procedure involves applying the tetrazolium salt to the matrix from its solution in an organic solvent and after drying, applying the reagent system to the matrix from its aqueous solution to which has been added hexanesulfonate as wetting agent. It would have been obvious to one having ordinary skill in the art to modify Terashima to apply the organic solvent first to the spreading layer then thereafter apply the reagent system because it has been shown from above that applying the organic solvent first then applying the reagent provides uniformly dispersed reagent in the spreading layer.

***Response to Arguments***

Applicant's arguments with respect to claims 3-8 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



November 10, 2005



Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700